MAY 2 4 2001

InjecTx

510(K) Summary of Safety and Effectiveness for the BioSling- Bioabsorbable Polymer Sling and Surgical Mesh (K010533)

A. Submitter Information

Submitter's Name:	Prosurg, Inc./InjecTx, Inc.
Address:	2193 Trade Zone Blvd. San Jose, Ca. 95131
Telephone:	408-945-4044
Fax:	408-945-1390
Contact Person:	Ashvin Desai
Date of Preparation:	May 22, 2001

B. Device Name

BioSling™- Bioabsorbable Polymer Sling & Surgical Mesh

C. Predicate Device Name

Trade Name: TVT (Tension Free Vaginal Tape) Prolene Polypropylene Mesh

D. Device Description

The BioSling™- Bioabsorbable Polymer Sling and Surgical Mesh consists of a bioabsorbable polyester material, which can be surgically inserted around the urethra to support the bladder neck and urethra for treatment of incontinence.

The BioSling™- Bioabasorbable Polymer Sling is biocompatible and is made from similar materials widely used as absorbable sutures and clips. The bioabsorbable polymer sling provides additional support to weak muscle or hypermobile urethra.

E. Intended Use

The BioSling™- Bioabsorbable Polymer Sling and Surgical Mesh is an implant that is intended for the treatment of urinary incontinence resulting from urethral hypermobility or ISD and for implantation to reinforce soft tissues where weakness exists in the urological, gynecological or gastroenterological anatomy. This includes, but is not limited to, the following procedures: pubourethral support and bladder support, urethral and vaginal prolapse repair, colon and rectal prolapse repair, reconstruction of the pelvic floor and secral colposuspension.

F. Safety and Effectiveness

Biocompatibility and bench testing have been completed to support the safety and effectiveness of the BioSling™-Device for its intended use. The biocompatibility test results show that the material used in the design and manufacture of the device are non-toxic and non-sensitizing to biological tissues consistent with their intended use. Laboratory test results demonstrate that the materials chosen and the design utilized in manufacturing the BioSling™ Bioabsorbable Polymer Sling and Surgical Mesh will meet the established specifications necessary for consistent performance during their intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 24 2001

Mr. Ashvin Desai
President
InjecTx, Inc.
2195 Trade Zone Boulevard
San Jose, California 95131

Re: K010533
Trade/Device Name: BioSling - Bioabsorbable Sling and Surgical Mesh
Regulation Number: 878.3300
Regulatory Class: II
Product Code: FTL
Dated: February 20, 2001
Received: February 23, 2001

Dear Mr. Desai:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K010533

Device Name: BioSling- Bioabsorbable Sling and Surgical Mesh

Indications For Use:

The BioSling™-Bioabsorbable Polymer Sling and Surgical Mesh is an implant that is intended for the treatment of urinary incontinence resulting from urethral hypermobility or ISD and for implantation to reinforce soft tissues where weakness exists in the urological, gynecological or gastroenterological anatomy. This includes, but is not limited to, the following procedures: pubourethral support and bladder support, urethral and vaginal prolapse repair, colon and rectal prolapse repair, reconstruction of the pelvic floor and secral colposuspension.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhoan

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K010533

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use___

(Optional Format 1-2-96)